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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,187	11/27/2001	Laurence McCarthy	FOC-001	3934

24353 7590 04/07/2005

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EXAMINER	
HILL, MYRON G	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/996,187

Applicant(s)

MCCARTHY ET AL.

Examiner

Myron G. Hill

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21, 26-30 and 35-43 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7-21, 26-28 and 35-43 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3, see action.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This action is in response to paper filed 10/22/04.

The following claims are under consideration: claims 1, 2, 7-21, 26-28, 30, and 35-43.

#### ***Information Disclosure Statement***

Signed and initialed copies of the IDS papers filed 20 August 2004, 22 October 2004, and 30 November 2004 are enclosed.

#### ***Claim Objections***

Claim 8 is objected to because of the following informalities: "an messenger" should be "a messenger" and "is" is missing before the phrase. Appropriate correction is required.

#### ***Rejections Withdrawn***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

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The rejection of claims 1, 2, 7- 21, 26- 28, and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The Applicant has amended the claims and the rejection is withdrawn.

The rejection of claims 1, 2, 7- 21, 26- 28, and 30 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting the phenotype of a viral polymerase and its resistant to a compound, does not reasonably provide enablement for all disease states and bioactive compounds associated with those disease states is withdrawn.

The Applicant has amended the claims and the rejection is withdrawn.

The rejection of claims 1, 2, 7- 21, 26- 28, and 30 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

The Applicant has amended the claims and the rejection is withdrawn.

***Claim Rejections - 35 USC § 101***

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The rejection of claims 1, 2, 7- 21, 26- 28, and 30 under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility is withdrawn.

The Applicant has amended the claims and the rejection is withdrawn.

***Claim Rejections - 35 USC § 102***

The rejection of claims 1, 2, 15, 16, 19- 21, and 30 under 35 U.S.C. 102(b) as being anticipated by Lardner *et al.* (Science Vol. 246, pages 1155- 1158, from IDS) is withdrawn.

The Applicant has amended the claims and the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

Claims 1, 11, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lardner *et al.*, as applied above, and further in view of either Promega Catalog or Invitrogen Catalog.

***Rejections Maintained***

***Claim Rejections - 35 USC § 102***

Claims 1, 2, 9, 11, 14-16, 19, 20, 26, 27, and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Oon *et al.* (WO 00/18958 from IDS).

Applicant argues that Oon et al. does not teach a functional activity of HBV pol and does not show that the HBV pol is functional. Applicant argues that Oon et al. only teach a static activity and do not show that the polymerase is active.

Applicant's arguments have been fully considered and not found persuasive.

Page 12, line 24- page 25, line 2 defines the term detecting the phenotype and this includes "observable physical or biochemical characteristics of a bioactive molecule". The assay of Oon et al. measures the phenotype of a bioactive molecule.

The argument that it does not show polymerase activity is not commensurate in scope with the claims and the specification discloses that the whole open reading frame was amplified (page 7 lines 16-17) and thus it would be expected to have polymerase activity. The activity shown by Oon et al. is not static but a function of the polymerase enzymatic activity that incorporates the labeled nucleotide (page 17 lines 3-5)

Thus, Oon *et al.* anticipate the claimed invention.

### **NEW REJECTIONS**

#### ***Claim Rejections - 35 USC § 102***

Claims 1, 2, 7, 9, 10, 12-16, 19-21, 26, 27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Cihlar *et al.* (Prot Exp and Pur 1997 Vol 11, pages 209-218, from IDS).

The claims are drawn to a method of producing and evaluating a bioactive molecule comprising providing a nucleic acid sequence encoding the bioactive molecule, expressing the bioactive molecule, contacting the bioactive molecule with a compound, and detecting the phenotype in the presence or absence of the compound.

Cihlar *et al.* teach a method of producing and evaluating a bioactive molecule comprising providing a nucleic acid sequence encoding the bioactive molecule, expressing the bioactive molecule including pcr, second nucleic acid sequence regulatory element, in vitro TNT reaction, and enzymatic activity (page 211-212 and Figures 2, 5, and 7), contacting the bioactive molecule with a compound, and detecting the phenotype in the presence or absence of the compound (Table 1). Cihlar *et al.* use the in vitro product directly without purification (page 212, column 1, end of first part paragraph).

Thus, Cihlar *et al.* anticipate the claimed invention.

### ***Claim Rejections - 35 USC § 103***

Claims 1, 8, 11, 15, 17, 18, 28, and 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cihlar *et al.* (Prot Exp and Pur 1997 Vol 11, pages 209-218, from IDS).

The claims are drawn to a method of producing and evaluating a bioactive molecule comprising providing a nucleic acid sequence encoding the bioactive molecule, expressing the bioactive molecule, contacting the bioactive molecule with a

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compound, and detecting the phenotype in the presence or absence of the compound with the added limitations of RNA template, nested pcr, purification motif, and method that requires nested pcr, and a dependent claim of the modified method that proceeds without purification of the amplified nucleic acid product.

Cihlar *et al.* teach the invention essentially as claimed as discussed above.

One of ordinary skill in the art at the time of invention would have been motivated to modify the assay of Cihlar *et al.* with molecular techniques that were well known in the art to suit the specifics of the assay being used. One of ordinary skill in the art at the time of invention would have been motivated to use a purification motif to purify product between steps or detect bioactive molecule during the assay. One of ordinary skill in the art at the time of invention would have known that nested pcr was well known in the art to increase yield of an amplified nucleic acid product especially when the sample does not contain a high titer of the desired nucleic acid, such as when the sample is limited or the agent is rare (being able to detect single/few copies of HCV in 1ml of blood). One of ordinary skill in the art at the time of invention would have known that mRNA (or poly + RNA) could be used as template if the bioactive molecule was mRNA and amplified by rt-pcr. One of ordinary skill in the art at the time of invention would have known that both prokaryotic and eukaryotic transcription/translation system were available and could be used.

Thus, it would have been *prima facie* obvious to modify the assay of Cihlar *et al.* with other art known techniques with the expectation of success of being able to detect



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the functional activity of a microbial bioactive molecule in the presence or absence of a compound with the expectation of success.


### ***Conclusion***


No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

  
Myron G. Hill  
Patent Examiner  
31 March 2005

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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4/4/05